UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF JOHN MIKLOS, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this memorandum in support of their motion to exclude certain opinions of John Miklos, M.D.

INTRODUCTION

Dr. Miklos is a pelvic surgeon and urogynecologist in Georgia who has experience installing and removing sling systems and who has rendered opinions regarding Defendants' TVT Secur device.[1] (*See* Dr. Miklos's curriculum vitae and Expert Report ("Miklos Rep."), attached as Exhibits B & C). Plaintiffs, however, hope to elicit testimony from Dr. Miklos about topics that are entirely outside his professional education, training and experience and therefore outside his area of competence. Moreover, his general causation opinions are unreliable and largely irrelevant.

Specifically, the Court should preclude Dr. Miklos from testifying regarding:

[1] One plaintiff who was implanted with Defendants' Prolift device has designated Dr. Miklos as a general expert in her case. *See* Exhibit A. Dr. Miklos has not produced *any* expert reports on the Prolift device in this Wave, however, and he should therefore be excluded as an expert on Prolift in that case on this ground alone.

- Alleged design defects in the TVT Secur that are not supported by reliable scientific evidence.
- "Safer" alternative products whose comparative safety and efficacy have not been quantified.
- Alleged inadequate warnings that he is not qualified to address.
- Alleged inadequate training and clinical studies that he is not qualified to address.
- Defendants' knowledge, state of mind or intent.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014). The Supreme Court's decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), precludes "engagement of 'expert' witnesses whose intended role is more to argue the client's cause from the witness stand than to bring the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit." *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004). Plaintiffs seek to do precisely that through the testimony of Dr. Miklos. While Dr. Miklos may be qualified to render opinions about pelvic surgery, he has no specialized knowledge or expertise that would substantially assist the jury as it relates to other areas.

Dr. Miklos opines that: 1) the TVT Secur was defectively designed; 2) there were safer alternative products; 3) the warnings contained in the TVT Secur Instructions for Use (IFU) were inadequate; 4) the Defendants failed to adequately study or train physicians regarding the TVT Secur; and 5) the Defendants were aware of the undisclosed risks. (Miklos Rep. at 13-25). Each of these opinions is flawed and should be excluded.

I. Dr. Miklos's opinion that the TVT-Secur is defectively designed is unreliable.

"Expert opinions premised upon speculation and conjecture are insufficient to create a genuine issue of material fact to survive summary judgment." *Dana Corp. v. Am. Standard, Inc.*, 866 F. Supp. 1481, 1499 (N.D. Ind. 1994). An expert's simple *ipse dixit* is insufficient to establish a matter; rather, the expert must explain the basis of his statements to link his conclusions to the facts. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999); *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011).

Dr. Miklos enumerates several alleged defective design elements of the TVT Secur product: the mechanism for insertion; tension and fixation issues; the "sharp edges" of the insertion device; and the release mechanism. Miklos Rep. at 5, 13-14.[2] Dr. Miklos's opinions regarding these supposed defects are not based on any reliable methodology but are instead mere *ipse dixit.* Moreover, he lacks the requisite expertise to opine regarding certain characteristics of the TVT-Secur product.

Dr. Miklos is neither qualified to opine, nor does he have evidence to support, any opinion addressing the biocompatibility characteristics of the mesh used in the TVT Secur. Although Dr. Miklos is a skilled surgeon, he admittedly is not an expert in biocompatibility issues. He has had no training or education on biomaterial medical device design, as he testified previously when deposed on his general opinions on the TVT Secur. *See* Feb. 6, 2015 Deposition of John R. Miklos, M.D., *Garcia v. Walss, et al.*, No. 2013-DCL-3511-D (Dist. Ct. 103d Judicial Dist., Cameron Cnty., Tex.) ("2/6/15 Dep.") at 246:23-25 (attached hereto as

[2] Dr. Miklos has not offered opinions regarding mesh degradation, fraying, or particle loss, and admits he is not qualified to opine on those topics. 2/6/15 Dep. at 199:10-200:13.

Exhibit D).[3] He has never been involved in any bench research on polypropylene mesh, and he has no training or education in polymer chemistry. *Id*. at 247:3-8. His lack of expertise in this area necessarily impacts the permissible scope of his testimony.

Nevertheless, Dr. Miklos testified that laser cutting mesh changes the properties of the mesh, and that Ethicon internal documents say that it will decrease fraying but they have not done any studies on it. 2/6/15 Dep. at 192:6-15. Yet, he acknowledges he has not seen any of the Ethicon studies, just the emails; he does not know if he has any problem with the laser cut mesh because it has not been utilized enough to know. *Id*. at 192:1-193:16 (Q: You don't have any problem with laser cut mesh, do you? A. I don't know.) He also concedes he has no scientific evidence to say that the laser cut mesh is any different as it reacts in the body as compared to mechanical cut mesh. 2/6/15 Dep. at 193:21-25 (Q: You don't have any scientific base to say that the laser cut mesh is any different as it reacts in the human body as compared to the mechanical cut mesh? A: No, you're correct.) Indeed, he agrees that the polypropylene mesh is the "best tolerated material to date with the least amount of complications", and that infection and rejection of the material are "very, very rare" in a skilled surgeon's hands. 2/6/15 Dep. 195:8-16.

Dr. Miklos's opinions regarding laser-cut mesh, to the extent he intends to offer them in the present proceedings, are not based on reliable studies or methodology. Dr. Miklos employs no methodological standards to judge mesh stiffness and has performed no testing to show that the mesh cutting method causes adverse clinical outcomes. He does not point to any study showing any difference between laser cut and machine cut mesh in patients. His regurgitation of

[3] Dr. Miklos is also former CEO of RockHard Laboratories, LLC, maker of "Rockhard Weekend" male sex enhancement pill –the subject of a class action lawsuit. *See* 2/6/15 Dep. at 104-107 (discussing involvement in RockHard Laboratories and successor company, Food, Drug, & Mass).

internal company documents requires no expertise at all. *See also Sullivan v. Alcatel-Lucent USA Inc.*, No. 12 C 07528, 2014 WL 3558690, at *5 (N.D. Ill. July 17, 2014) (excluding expert testimony based on internal company documents, observing that the expert "simply reads and interprets documents" but "does not draw on any expert qualifications or experience. As such, his readings and interpretations are merely gratuitous, and would be unhelpful to a prospective jury."). Dr. Miklos's review of company emails, memos and anecdotal experiences falls far short of sound scientific method. His "method" certainly does not rise to "same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire* 526 U.S. at 152.

Likewise, Dr. Miklos's criticisms of TVT Secur's alleged intolerable failure rates due to purported defects such as the insertion and retraction mechanism, as well as the Ethisorb fixation mechanism are unsupported by any reliable scientific evidence. Miklos Rep. at 8-9, 13-14. To the contrary, one TVT Secur study he was directly involved in concluded that the TVT Secur was "as efficacious as its predecessors." 2/6/15 Dep. at 184:9-18 & Ex. 18 thereto (attached as Ex. D). Although Dr. Miklos did not draft the abstract describing this study, and, as of his deposition on the TVT Secur, purports to disagree with its conclusions, prior to that litigation he never publicly disavowed the published conclusion nor requested a public correction. Miklos Dep. at 184:9-185:15. Moreover, the information published on his own website as late as February 3, 2015 touts TVT Secur success rates as "averag[ing] in the 60-70% range". 2/6/15 Dep. at 178:23-179:6 & Ex. 17 thereto. For purposes of the present litigation, however, Dr. Miklos abandons these prior public statements, now opining that the "TVT-S insertion method and design often caused . . . lower success rates than other available SUI products." Miklos Rep. at 13. Such litigation-driven testimony is inherently unreliable and should be excluded.

Furthermore, in his deposition, Dr. Miklos acknowledged that there are several randomized clinical trials (which are the highest level of data on TVT Secur) that show that the device is effective. (Exhibit E. April 8, 2016 Deposition of John Miklos, M.D., in No. 2:12-MD-02327 (S.D. W. Va.) ("4/8/16 Dep.") at 28:9-29:3). For example, he acknowledged several studies with efficacy rates of 80-100%, and he acknowledged other randomized clinic trials in which the TVT Secur was demonstrated to be as efficacious as TVT or TVT-O, which Dr. Miklos states are effective and safe. (4/8/16 Dep. at 28:9-29:3; *see also* 2/6/15 Dep. at 178:9-179:4; 184:9-18; 342:21-23). Dr. Miklos acknowledged that the surgeon's skill set and technique are the most important factors in the use of a device, and not the device itself. (4/8/16 Dep. at 11:7-12; *see* 2/6/15 at 147:12-148:3). He acknowledged that TVT Secur works in various surgeons' hands. (2/6/15 Dep. at 195:8-16; 290:23-291:). Thus, Dr. Miklos's own testimony belies his opinion that TVT Secur is defective, as he fails to rule out surgeon skill and technique as the reason why some studies had lower efficacy.

As to his criticisms of the Ethisorb in particular, he admits that he does not know one way or another whether the Ethisorb is effective or defective. (2/6/15 Dep. at 296:21-298:15). He cites no scientific studies, peer-reviewed or otherwise, to support his speculative criticisms of Ethisorb. His opinions regarding the insertion and release mechanisms are similarly lacking. He cites no supporting literature, and his opinions are conclusory, speculative and unsupported by evidence. Such testimony is not helpful to the jury and should be excluded.

II. Dr. Miklos's opinion that there were safer alternative products is subjective and unreliable.

In the present case, Dr. Miklos opines that there were a number of other equally effective alternative products to treat stress urinary incontinence ("SUI") than the TVT Secur (Miklos

Rep. at 8, 13, 14, 21). In particular, he believes that TVT Secur was "considerably inferior to retropubic and inside-out trans obturator slings." (*Id.* at 12).

Dr. Miklos has no basis to support any conclusion that these constituted safer alternative designs. He did not disclose any testing, calculations, engineering analysis, or publications that would support this opinion. In fact he admits that because the TVT Secur uses only one small incision, it decreases the risk of injury. 2/6/15 Dep. at 196:23-197:1. Yet the first *Daubert* factor is whether the theory or technique employed by the expert can be and has been tested. *Daubert*, 509 U.S. at 591-95; *see Watkins v. Telsmith, Inc.*, 121 F.3d 984, 992 (5th Cir. 1997) (proposing alternative design requires more than "conceptualizing possibilities"); *see also Oglesby v. Gen. Motors Corp.*, 190 F.3d 244 (4th Cir. 1999) (affirming exclusion of mechanical engineer's expert testimony where "he did not know the type or composition of the plastic" at issue, failed to ask the manufacturer, analyze or test the part, and did not apply any calculations). Further, this Court has also excluded expert opinions when the expert acknowledges that medical literature contrary to that opinion existed but failed to explain why he or she disagreed with it. *See Mathison v. Bos. Sci. Corp.*, 2015 WL 2124991, at *7 (excluding opinion of Dr. Michael Thomas Margolis regarding complication rates of women with polypropylene mesh where Dr. Margolis failed to provide "an adequate explanation" for why he disagreed with contrary medical literature). Dr. Miklos has likewise failed to explain why a product with decreased risk of injury is nevertheless not as safe as supposed safer alternative products.

Furthermore, Dr. Miklos opines that the TVT Secur can cause erosions. (Miklos Rep. at 13, 24). Yet he agreed in his deposition that mesh erosion can occur regardless of the product used. 2/6/15 Dep. at 276:5-14. Nevertheless, he opines that the TVT-Secur has a greater risk of erosion. *Id.* When asked to quantify the risk, he said it was "statistically significant" but cannot

"give it a quantification." 2/6/15 Dep. at 278:22-279:5; 279:25-280:17 (Q: Based on everything you've read, can you give me any percentage of what the risk is different compared --- comparing TVT-Secur, TVT-O, and TVT-R? A: No.) (objections of counsel omitted); *see also* 4/8/16 Dep. at 47:18-49:4 (conceding that a level one review and meta-analysis of randomized control trials showing rate of exposure of TVT was lower and not significantly different than retropubic or obturator devices). Dr. Miklos's opinion should be excluded because he cannot point to any reliable, verifiable basis for the comparison of safety rates of TVT-Secur versus these other products.

In summary, Dr. Miklos's testimony does not link his conclusions to the analysis, if any, that he performed to determine that retropubic and inside-out trans obturator slings are indeed more effective. His theory relies heavily upon his own subjective interpretation, and has not been generally accepted within the relevant scientific community. *See Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311 (2d Cir. 2008) (rejecting expert's conclusory statement where it was not accompanied by "any evidentiary citation" or followed by any elaboration of the expert's reasoning); *Hudgens v. Bell Helicopters/Textron*, 328 F.3d 1329, 1344 (11th Cir. 2003) ("[A]n expert's failure to explain the basis for an important inference mandates exclusion of his or her opinion."). Therefore, Dr. Miklos's testimony that there is no evidence of safer alternative products is unreliable and should be excluded.

III. This Court should exclude Dr. Miklos's opinions regarding the adequacy of the TVT Secur IFU.

Dr. Miklos contends that the IFU which accompanied the TVT Secur was defective and failed to provide adequate warnings and information to treating surgeons. Miklos Rep. at 14-24. These opinions should be excluded on several grounds.

First, Dr. Miklos has no expertise in medical device warnings or regulatory requirements.

Second, he fails to identify any reliable scientific evidence establishing that the risks he identifies were actually related to the TVT Secur product. His opinion is nothing more than subjective *ipse dixit*, which is unreliable, inadmissible, and should be excluded.

A. Dr. Miklos is not qualified to testify about product warnings.

Because Dr. Miklos is not a biocompatibility expert, as discussed *supra*, he is not qualified to testify to the adequacy of warnings regarding biomaterial characteristics related to mesh degradation, stiffness, weight or porosity. Dr. Miklos should not be allowed to testify about failure to warn of alleged design defects he is not competent to identify. In other mesh litigation, the proffered experts' qualifications to opine about biomaterial properties such as degradation and porosity have been closely scrutinized and such testimony has been limited to experts with extensive biomaterial and biomechanical engineering education and experience. *See In re C.R. Bard, Inc., Pelvic Repair Sys. Liab. Litig.*, 948 F. Supp. 2d 589, 623 (S.D. W. Va. 2013) (allowing physician testimony regarding biomechanical analysis of mesh only after establishing that physician had two engineering degrees, had practiced as an engineer for twelve years, and had focused on studying biomechanical analysis of pelvic floor structures and the pelvic floor from an engineering perspective for ten years); *id.* at 633 (expressing "concerns about [physician's] qualifications to testify specifically as to the properties of polypropylene" mesh, but allowing testimony only after establishing that physician not only had a biomedical engineering degree, but also routinely evaluated biomaterials, developed new biomaterials and modified existing biomaterials, and had specific experience with polymeric material).

Moreover, Dr. Miklos is not otherwise qualified to testify regarding the adequacy of the warnings accompanying the TVT Secur because he has absolutely no expertise in that area. Dr. Miklos has no demonstrated or identified experience in preparing IFU documents and no training

related to developing warnings or labeling. He admits that he is not a FDA regulatory expert. 2/6/15 Dep. at 241:10-11. He acknowledges that the FDA looks at things differently than he does. *Id*. at 241:2-5. His experience as a urogynecologist and surgeon is not sufficient to inform his opinions regarding the highly regulated area of prescription drug labeling and warnings. *See Cisson v. C.R. Bard, Inc.*, 948 F. Supp.2d 589, 611 (S.D. W. Va. 2013) (excluding plaintiff's expert, Dr. Bob Shull, on warnings and labels for medical devices: "[d]espite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process."); *Tyree v. Boston Scientific Corp.*, 2014 WL 5486694, at *36-37 (S.D. W. Va. Oct. 29, 2014) (Dr. Donald Ostergard (urogynecologist), although qualified to opine on the design of the sling in question, was not qualified to opine on product warnings and FDA compliance); *Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion)

Because Dr. Miklos is not qualified to opine regarding the adequacy of the TVT Secur IFU, his opinions as to a failure to warn about these alleged defects should be excluded.

B. Dr. Miklos does not identify a reliable basis for his opinions.

As an alternative ground for exclusion, Dr. Miklos's expert report does not set forth a reliable basis for his opinions that the TVT Secur's IFU is inadequate. He cites no scientific evidence that the polypropylene mesh used in the TVT Secur actually shrinks or contracts, causes foreign body reactions, vaginal deformation, or has higher failure and revision rates. (Miklos Rep. at 20-22). In fact, Dr. Miklos believes that mesh bladder sling surgeries "are considered the Gold standard . . . of care for urinary leakage." 2/6/15 Dep. at 128:2-7. He

agrees with the American Urogynecology Society and Society of Female Urology that "complications for mesh bladder sling are minimal." 2/6/15 Dep. at 129:7-17. He prefers Ethicon's Prolene polypropylene mesh (specifically the TVT retropubic device and more recently the TVT Exact device) and admits that it is the "best tolerated material to date with the least amount of complications." *Id.* at 195:8-12; *see also* 4/8/16 Dep. at 27:16-21; 29:19-30:2 (expressing opinions that TVT retropubic and TVT-O full-length sling are more effective as TVT Secur); *id.* at 12:12-14 (describing current use of TVT Exact and retropubic sling).

IV. Dr. Miklos's opinions regarding inadequate training are not relevant.

Although Dr. Miklos opines that Defendants failed to provide adequate training (Miklos Report at 16), he acknowledges that Ethicon had no obligation to provide training. The FDA places the obligation to obtain specialized training on the treating physician, a fact that Dr. Miklos concedes. 2/6/15 Dep. at 204:19-24. He agrees that companies like Ethicon sell almost exclusively to hospitals and that it is the hospital credentialing committee's job to make sure doctors are trained to do surgeries before credentials are given. 2/6/15 Dep. at 208:6-209:19. He agrees ultimately that it is the physician's judgment call as to whether he or she is competent and qualified to do the surgery. *Id*. at 209:21-25. He also agrees that it is not Ethicon's job to tell hospitals how to give privileges to doctors but they have to choose and train doctors of quality. *Id.* He admits that there is no regulatory agency mandating that companies like Ethicon conduct training. *Id*. at 211:11-19. Dr. Miklos's opinion that Ethicon failed to provide adequate training is irrelevant given his admissions that it was not required to in the first place.

Indeed, when shown the TVT Secur Key Procedural Steps document in his deposition for this Wave of cases, which was created to ensure that surgeons were using correct pathways and insertion techniques, among other things, Dr. Miklos testified that he was not familiar with this

document. 4/8/16 Dep. at 56:17-59:3. Dr. Miklos cannot testify that Ethicon's professional training and education was inadequate when he has not even reviewed its materials. His testimony is mere *ipse dixit*.

Additionally, instead of relying upon any particular expertise to opine regarding training, Dr. Miklos merely regurgitates information contained in internal Ethicon emails and documents and depositions of Ethicon employees. Miklos Rep. at 16-18. Such narrative testimony should be excluded as Dr. Miklos would merely be serving as "Plaintiffs' advocate rather than expert." *In re: Trasylol*, 709 F. Supp. 2d 1323, 1346-47 (S.D. Fla. 2010); *accord In re: Rezulin*, 309 F. Supp. 2d at 546 (excluding expert testimony intended merely to "provid[e] an historical commentary of what happened"); *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005) (stating that "an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence" and excluding expert's testimony, including expert's references to defendant's internal documents; *In re: Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding portions of an expert's report because it "presents a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory findings, and the deposition testimony of Merck employees").

V. The Court should exclude Dr. Miklos's opinions about Ethicon's knowledge, state of mind and alleged bad acts.

The Court should preclude Dr. Miklos from testifying about Ethicon's alleged knowledge and bad acts. For instance, Dr. Miklos states that "Ethicon knowingly failed to disclose the TVT-S's inadequacies" and that Ethicon "knew the TVT-S required extensive training." Miklos Rep. at 16, 21. There is nothing about Dr. Miklos's experience as a pelvic surgeon that affords him specialized knowledge or clairvoyance to testify about what Ethicon did or did not know or

to speculate about what Ethicon supposedly never did. *See, e.g., In re: Diet Drugs Prods. Liab. Litig.*, 2000 U.S. Dist. LEXIS 9037, at *9 (E.D. Pa. 2000) (precluding the plaintiffs' experts from testifying as to the defendants' intent); *In re: Rezulin*, 309 F. Supp. 2d at 547 ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony"); *BorgWarner, Inc. v. Honeywell Int'l, Inc.*, 750 F. Supp. 2d 596, 611 (W.D.N.C. 2010) (precluding a party's expert witness from opining about a party's intent). To the extent that Dr. Miklos's opinions are based on his review of documents that Plaintiffs' counsel selectively presented to him, these concern mere "lay matters which a jury is capable of understanding and deciding without the expert's help." *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

Recently, this Court precluded another physician from offering similar testimony. In *Lewis v. Ethicon*, No. 12-cv-4301, 2014 WL 186872 (S.D. W. Va. Jan 15, 2014), this Court found that "expert opinions on Ethicon's knowledge or state of mind are not helpful to the jury" and that although the expert in issue was "qualified as a physician; he is not qualified by 'knowledge, skill, experience, training or education' to opine on Ethicon's state of mind or knowledge." *Id.*, at *15. And in *In re: C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D. W. Va. 2013), one of the plaintiffs' experts, Dr. Bob Shull, a urogynecologist like Dr. Miklos, intended to testify about "Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics." *Id.* at 610. This Court, however, found as follows:

> While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions – assuming the opinions are otherwise admissible – Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony . . . the question of intent is a

> classic jury question and not one for the experts.") (internal quotation marks omitted); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Accordingly, I FIND that Dr. Shull's opinions related to Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics should be excluded.

Id. at *611 (emphasis added); *see also Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 52444287, at *7-8 (S.D. W. Va. Feb. 15, 2012) (S.D. W. Va. 2012) (Johnston, J.) (excluding an expert from testifying as to product defect, where expert's opinion was not based on his experience or education, but rather was based on other experts' testimony and the defendant's corporate documents).

For the same reasons that this Court precluded Dr. Shull from testifying about such matters, the Court should also preclude Dr. Miklos from testifying about these matters.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Miklos's testimony consistent with the foregoing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 21, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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